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WORLD INTELLECTUAL PROPERTY ORGANIZATION
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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61K 7/16

A1

(11) International Publication Number: WO 92/10992

(43) International Publication Date: 9 July 1992 (09.07.92)

(21) International Application Number: PCT/US91/09377

(22) International Filing Date: 13 December 1991 (13.12.91)

(30) Priority data:
630,094 19 December 1990 (19.12.90) US

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(81) Designated States: AT, AT (European patent), AU, BB, BE (European patent), BF (OAPI patent), BG, BJ (OAPI patent), BR, CA, CF (OAPI patent), CG (OAPI patent), CH, CH (European patent), CI (OAPI patent), CM (OAPI patent), CS, DE, DE (European patent), DK, DK (European patent), ES, ES (European patent), FI, FR (European patent), GA (OAPI patent), GB, GB (European patent), GN (OAPI patent), GR (European patent), HU, IT (European patent), JP, KP, KR, LK, LU, LU (European patent), MC (European patent), MG, ML (OAPI patent), MN, MR (OAPI patent), MW, NL, NL (European patent), NO, PL, RO, SD, SE, SE (European patent), SN (OAPI patent), SU*, TD (OAPI patent), TG (OAPI patent).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: ORAL COMPOSITIONS EFFECTIVE AGAINST PLAQUE AND GINGIVITIS

(57) Abstract

Disclosed are oral compositions which are effective against plaque and gingivitis and contain a noncationic water insoluble antibacterial agent.

+ DESIGNATIONS OF "SU"

Any designation of "SU" has effect in the Russian Federation. It is not yet known whether any such designation has effect in other States of the former Soviet Union.

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ORAL COMPOSITIONS EFFECTIVE AGAINST PLAQUE AND GINGIVITIS

Douglas Charles Mohl

TECHNICAL FIELD

The present invention relates to oral compositions which provide antiplaque and antigingivitis benefits as well as being effective against other anaerobic infections of the mouth.

Plaque induced diseases, including periodontitis and gingivitis, are believed to involve anaerobic bacterial infections. Periodontal disease affects the periodontium, which is the investing and supporting tissue surrounding a tooth (i.e., the periodontal ligament, the gingiva, and the alveolar bone). Gingivitis and periodontitis are inflammatory disorders of the gingiva and the periodontal ligament, respectively. Gingivosis and periodontosis are more severe conditions involving degenerative disorders of the tissue. Combinations of inflammatory and degenerative conditions are termed periodontitis complex.

Periodontal disease is a major cause of tooth loss in adults. Tooth loss from periodontal disease is a significant problem beginning at age 35, but even by age 15 it is estimated that about 4 out of 5 persons already have gingivitis and 4 out of 10 have periodontitis.

While good oral hygiene, as achieved by brushing the teeth with a cleansing dentifrice, may help reduce the incidence of periodontal disease, it does not necessarily prevent or eliminate its occurrence. This is because microorganisms contribute to both the initiation and progress of periodontal disease. Thus, in order to prevent or treat periodontal disease, these microorganisms must be suppressed by some means other than simple mechanical scrubbing. Towards this end, there has been a great deal of research aimed at developing therapeutic dentifrices, mouthwashes, and methods of treating periodontal disease which are effective in suppressing these microorganisms.

The use of noncationic, water-insoluble antibacterial agents in oral products is disclosed in a number of references. One such reference is U.S. Patent 4,022,889 to Vinson et al. Vinson describes compositions containing zinc salts and antibacterial agents such as halogenated salicylanilides and halogenated hydroxydiphenyl ethers.

Another reference disclosing noncationic water-insoluble antibacterial agents is U.K. Patent Application GB 2,200,551, published August 10, 1988. In addition to the antibacterial, the compositions contain a molecularly dehydrated polyphosphate salt. The salt is stated to improve the effectiveness of the antibacterial. Another reference disclosing noncationic water-insoluble antibacterials in oral compositions is U.S. 4,894,220, January 16, 1990 to Nabi et al. This reference teaches the use of solvents and polymers to enhance the antibacterial's effect.

Still another reference disclosing such antibacterials combined with polyethylene glycols in oral compositions is European Patent Application 02,220,890, May 6, 1987. All prior art references are incorporated herein by reference in total.

It has now been found that the bioavailability and effectiveness of the antibacterial can be improved by incorporating the antibacterial, a linear anionic polycarboxylate and a polyethylene glycol into the composition.

It is therefore an object of the present invention to provide improved oral care products containing specific antibacterial agents.

It is a further object of the present invention to provide more effective products for treating diseases of the oral cavity.

It is still a further objective to provide methods for treating diseases of the oral cavity.

These and other objects will become readily apparent from the detailed disclosure which follows.

All percentages and ratios used herein are by weight unless otherwise specified. Also, all measurements referred to herein are made at 25°C in the composition unless otherwise specified.

SUMMARY OF THE INVENTION

The present invention, in certain aspects, embraces oral care product containing water-insoluble, noncationic antibacterial agents, a polyethylene glycol solvent and an anionic linear, polycarboxylate.

The present invention also encompasses a method for treating diseases of the oral cavity using noncationic water insoluble antibacterial agents.

By "oral compositions" as used herein means a product which in the ordinary course of usage is not intentionally swallowed for

purposes of systemic administration of particular therapeutic agents, but is rather retained in the oral cavity for a time sufficient to contact substantially all of the dental surfaces and/or oral tissues for purposes of oral activity.

By "safe and effective amount" as used herein means sufficient amount of material to provide the desired benefit while being safe to the hard and soft tissues of the oral cavity.

By the term "comprising", as used herein, is meant that various additional components can be conjointly employed in the compositions of this invention as long as the listed materials perform their intended functions.

By the term "carrier", as used herein, is meant a suitable vehicle which is pharmaceutically acceptable and can be used to apply the present compositions in the oral cavity.

DETAILED DESCRIPTION OF THE INVENTION

The present invention in certain aspects involves the use of water-insoluble, noncationic antibacterials with a polyethylene glycol solvent and a carboxyvinyl polymer having molecular weight of 3,000,000 or greater. The essential and optional components of the compositions are made using the process described in detail below.

Antibacterial Agents

Given below are examples of antibacterial agents useful in the compositions of the present invention which are water insoluble and noncationic.

Halogenated Diphenyl Ethers

2',4,4'-trichloro-2-hydroxy-diphenyl ether (Triclosan)

2,2'-dihydroxy-5,5'-dibromo-diphenyl ether.

Phenolic Compounds (including phenol and its homologs, mono- and poly-alkyl and aromatic halophenols, resorcinol and its derivatives, bisphenolic compounds and halogenated salicylanilides).

Phenol and its Homologs

Phenol

2 Methyl	- Phenol
3 Methyl	- Phenol
4 Methyl	- Phenol
4 Ethyl	- Phenol
2,4-Dimethyl	- Phenol

2,5-Dimethyl - Phenol
3,4-Dimethyl - Phenol
2,6-Dimethyl - Phenol
4-n-Propyl - Phenol
4-n-Butyl - Phenol
4-n-Amyl - Phenol
4-tert-Amyl - Phenol
4-n-Hexyl - Phenol
4-n-Heptyl - Phenol

Mono- and Poly-Alkyl and Aromatic Halophenols

p-Chlorophenol
Methyl - p-Chlorophenol
Ethyl - p-Chlorophenol
n-Propyl - p-Chlorophenol
n-Butyl - p-Chlorophenol
n-Amyl - p-Chlorophenol
sec-Amyl - p-Chlorophenol
n-Hexyl - p-Chlorophenol
Cyclohexyl - p-Chlorophenol
n-Heptyl - p-Chlorophenol
n-Octyl - p-Chlorophenol

o-Chlorophenol
Methyl - o-Chlorophenol
Ethyl - o-Chlorophenol
n-Propyl - o-Chlorophenol
n-Butyl - o-Chlorophenol
n-Amyl - o-Chlorophenol
tert-Amyl - o-Chlorophenol
n-Hexyl - o-Chlorophenol
n-Heptyl - o-Chlorophenol
o-Benzyl - p-Chlorophenol
o-Benxyl-m-methyl - p-Chlorophenol
o-Benzyl-m, m-dimethyl - p-Chlorophenol
o-Phenylethyl - p-Chlorophenol
o-Phenylethyl-m-methyl - p-Chlorophenol
3-Methyl - p-Chlorophenol
3,5-Dimethyl - p-Chlorophenol
6-Ethyl-3-methyl - p-Chlorophenol
6-n-Propyl-3-methyl - p-Chlorophenol

6-iso-Propyl-3-methyl - p-Chlorophenol
2-Ethyl-3,5-dimethyl - p-Chlorophenol
6-sec-Butyl-3-methyl - p-Chlorophenol
2-iso-Propyl-3,5-dimethyl - p-Chlorophenol
6-Diethylmethyl-3-methyl - p-Chlorophenol
6-iso-Propyl-2-ethyl-3-methyl - p-Chlorophenol
2-sec-Amyl-3,5-dimethyl - p-Chlorophenol
2-Diethylmethyl-3,5-dimethyl - p-Chlorophenol
6-sec-Octyl-3-methyl - p-Chlorophenol

p-Bromophenol
Methyl - p-Bromophenol
Ethyl - p-Bromophenol
n-Propyl - p-Bromophenol
n-Butyl - p-Bromophenol
n-Amyl - p-Bromophenol
sec-Amyl - p-Bromophenol
n-Hexyl - p-Bromophenol
cyclohexyl - p-Bromophenol

o-Bromophenol
tert-Amyl - o-Bromophenol
n-Hexyl - o-Bromophenol
n-Propyl-m,mDimethyl - o-Bromophenol

2-Phenyl Phenol
4-Chloro-2-methyl phenol
4-Chloro-3-methyl phenol
4-Chloro-3,5-dimethyl phenol
2,4-dichloro-3,5-dimethylphenol
3,4,5,6-terabromo-2-methylphenol
5-methyl-2-pentylphenol
4-isopropyl-3-methylphenol
5-Chloro-2-hydroxydiphenylmethane

Resorcinol and its Derivatives

Resorcinol
Methyl - Resorcinol
Ethyl - Resorcinol
n-Propyl - Resorcinol
n-Butyl - Resorcinol
n-Amyl - Resorcinol
n-Hexyl - Resorcinol

n-Heptyl - Resorcinol
n-Octyl - Resorcinol
n-Nonyl - Resorcinol
Phenyl - Resorcinol
Benzyl - Resorcinol
Phenylethyl - Resorcinol
Phenylpropyl - Resorcinol
p-Chlorobenzyl - Resorcinol
5-Chloro -2,4-Dihydroxydiphenyl Methane
4'-Chloro -2,4-Dihydroxydiphenyl Methane
5-Bromo -2,4-Dihydroxydiphenyl Methane
4'-Bromo -2,4-Dihydroxydiphenyl Methane

Bisphenolic Compounds

2,2'-methylene bis (4-chlorophenol)
2,2'-methylene bis (3,4,6-trichlorophenol)
2,2'-methylene bis (4-chloro-6-bromophenol)
bis (2-hydroxy-3,5-dichlorophenyl) sulphide
bis (2-hydroxy-5-chlorobenzyl) sulphide

Halogenated Salicylanilides

4',5-dibromosalicylanilide
3,4',5-trichlorosalcylanilide
3,4',5-tribromosalicylanilide
2,3,3',5-tetrachlorosalicylanilide
3,3',5-trichlorosalicylanilide
3,5-dibromo-3'-trifluoromethyl salicylanilide
5-n-octanoyl-3'-trifluoromethyl salicylanilide
3,5-dibromo-4'-trifluoromethyl salicylanilide
3,5-dibromo-3'-trifluoromethyl salicylanilide (Fluorophene)

Benzoic Esters

p-Hydroxybenzoic Acid
Methyl - p-Hydroxybenzoic Acid
Ethyl - p-Hydroxybenzoic Acid
Propyl - p-Hydroxybenzoic Acid
Butyl - p-Hydroxybenzoic Acid

Halogenated Carbanilides

3,4,4'-trichlorocarbanilide
3-trifluoromethyl-4,4'-dichlorocarbanilide
3,3',4-trichlorocarbanilide

The antibacterial agent is present in the oral compositions of the present invention in an effective antiplaque amount, typically about 0.01-5% by weight, preferably about 0.03-1%. The antibacterial agent is substantially water-insoluble, meaning that its solubility is less than about 1% by weight in water at 25°C and may be even less than about 0.1%. If an ionizable group is present solubility is determined at a pH at which ionization does not occur.

Polyethylene Glycols

The polyethylene glycols useful in this invention can be any of a wide range of molecular weights such as from about 100 to about 1,000, preferably from about 300 to about 600. The glycol is present in an amount of from about 1% to about 10%, preferably from about 3% to about 6%.

Anionic Linear Polycarboxylate

The anionic polymeric polycarboxylates employed herein are well known, being employed in the form of their free acids or partially or preferably fully neutralized water soluble alkali metal (e.g. potassium and preferably sodium) or ammonium salts. Preferred are 1:4 to 4:1 copolymers of maleic anhydride or acid with another polymerizable ethylenically unsaturated monomer, preferably methyl vinyl ether (methoxyethylene) having a molecular weight (M.W.) of about 30,000 to about 1,000,000. These copolymers are available for example as Gantrez (AN 139(M.W. 500,000), A.N. 119 (M.W. 250,000) and preferably S-97 Pharmaceutical Grade (M.W. 70,000), of GAF Corporation.

Other operative polymeric polycarboxylates include those such as the 1:1 copolymers of maleic anhydride with ethyl acrylate, hydroxyethyl methacrylate, N-vinyl-2-pyrollidone, or ethylene, the latter being available for example as Monsanto EMA No. 1103, M.W. 10,000 and EMA Grade 61, and 1:1 copolymers of acrylic acid with methyl or hydroxyethyl methacrylate, methyl or ethyl acrylate, isobutyl vinyl ether or N-vinyl-2-pyrrolidone.

Additional operative polymeric polycarboxylates disclosed in above referred to U.S. Patent Nos. 4,138,477 and 4,183,914, incorporated herein by reference, include copolymers of maleic anhydride with styrene, isobutylene or ethyl vinyl ether, polyacrylic, polyitaconic and polymaleic acids, and sulfoacrylic oligomers of M.W. as low as 1,000 available as Uniroyal ND-2.

Suitable generally are polymerized olefinically or ethylenically unsaturated carboxylic acids containing an activated carbon-to-carbon olefinic double bond and at least one carboxyl group, that is, an acid containing an olefinic double bond which readily functions in polymerization because of its presence in the monomer molecule either in the alpha-beta position with respect to a carboxyl group or as part of a terminal methylene grouping. Illustrative of such acids are acrylic, methacrylic, ethacrylic, alpha-chloroacrylic, crotonic, beta-acryloxy propionic, sorbic, alpha-chlorsorbic, cinnamic, beta-styrylacrylic, muconic, itaconic, citraconic, mesaconic, glutaconic, aconitic, alpha-phenylacrylic, 2-benzyl acrylic, 2-cyclohexylacrylic, angelic, umbellic, fumaric, maleic acids and anhydrides. Other different olefinic monomers copolymerizable with such carboxylic monomers include vinylacetate, vinyl chloride, dimethyl maleate and the like. Copolymers contain sufficient carboxylic salt groups for water-solubility.

The linear anionic polymeric polycarboxylate component is mainly a hydrocarbon with optional halogen and O-containing substituents and linkages as present in for example ester, ether and OH groups, and when present is generally employed in the instant compositions in approximate weight amounts of 0.05 to 3%, preferably 0.05 to 2%, more preferably 0.1 to 2%.

Water

Water is another essential component of this invention. Water employed in the preparation of commercially suitable compositions should preferably be deionized and free of organic impurities. Water generally comprises from about 10% to 50%, preferably from about 20% to 40%, by weight of the toothpaste compositions herein while mouthwashes contain from about 40% to about 95%. These amounts of water include the free water which is added plus that which is introduced with other materials as with sorbitol.

Optional Components

The compositions of the present invention may contain in addition to the above-listed components many others which will be somewhat dependent on the type of composition (mouthwashes, toothpastes, topical gels, prophylaxis pastes and the like). Toothpastes and mouthwashes are the preferred systems with

toothpastes being the most preferred.

Toothpastes contain as a major component an abrasive. The abrasive polishing material contemplated for use in the present invention can be any material which does not excessively abrade dentin. These include, for example, silicas including gels and precipitates, calcium carbonate, dicalcium orthophosphate dihydrate, calcium pyrophosphate, tricalcium phosphate, calcium polymetaphosphate, insoluble sodium polymetaphosphate, hydrated alumina, and resinous abrasive materials such as particulate condensation products of urea and formaldehyde, and others such as disclosed by Cooley et al. in U.S. Patent 3,070,510, December 25, 1962, incorporated herein by reference. Mixtures of abrasives may also be used.

Silica dental abrasives, of various types, can provide the unique benefits of exceptional dental cleaning and polishing performance without unduly abrading tooth enamel or dentin. Silica abrasive materials are also exceptionally compatible with sources of soluble fluoride and other ion sources. For these reasons they are preferred for use herein.

The silica abrasive polishing materials useful herein, as well as the other abrasives, generally have an average particle size ranging between about 0.1 and 30 microns, preferably 5 and 15 microns. The silica abrasive can be precipitated silica or silica gels such as the silica xerogels described in Pader et al., U.S. Patent 3,538,230, issued March 2, 1970 and DiGiulio, U.S. Patent 3,862,307, June 21, 1975, both incorporated herein by reference. Preferred are the silica xerogels marketed under the tradename "Syloid" by the W.R. Grace & Company, Davison Chemical Division. Preferred precipitated silica materials include those marketed by the J.M. Huber Corporation under the tradename, "Zeodent", particularly the silica carrying the designation "Zeodent 119". These silica abrasive are described in U.S. Patent 4,340,583, July 29, 1982, incorporated herein by reference.

The abrasive in the toothpaste compositions described herein is present at a level of from about 6% to about 70%, preferably from about 15% to about 30%.

Flavoring agents, as was noted earlier, can also be added to the dentifrice and other compositions of the present invention. Suitable flavoring agents include oil of wintergreen, oil of

peppermint, oil of spearmint, oil of sassafras, and oil of clove. Sweetening agents are also useful and include aspartame, acesulfame, saccharin, dextrose, levulose and sodium cyclamate. Flavoring and sweetening agents are generally used in the compositions herein at levels of from about 0.005% to about 2% by weight and may be used as a solvent for the antibacterials hereinbefore indicated.

In preparing toothpastes, it is necessary to add some thickening material to provide a desirable consistency. Preferred thickening agents are carboxyvinyl polymers, carrageenan, hydroxyethyl cellulose and water soluble salts of cellulose ethers such as sodium carboxymethyl cellulose and sodium carboxymethyl hydroxyethyl cellulose. Natural gums such as gum karaya, gum arabic, and gum tragacanth and polysaccharide gums such as xanthan gum can also be used. Colloidal magnesium aluminum silicate or finely divided silica can be used as part of the thickening agent to further improve texture. Thickening agents in an amount from 0.05% to 1.5% by weight of the total composition may be used.

It is also desirable to include a humectant in a toothpaste to keep it from hardening. Suitable humectants include glycerin, sorbitol, and other edible polyhydric alcohols at a combined level of from about 10% to about 70%.

Another preferred embodiment of the present invention is a mouthwash composition. Mouthwashes generally comprise from about 20:1 to about 2:1 of a water/ethyl alcohol solution and preferably other ingredients such as flavor, sweeteners, humectants and sudsing agents such as those described above. The humectants, such as glycerin and sorbitol give a moist feel to the mouth. Generally, on a weight basis the mouthwashes of the invention comprise 5% to 60% (preferably 10% to 25%) ethyl alcohol, 0% to 20% (preferably 5% to 20%) of a humectant, 0% to 2% (preferably 0.01% to 0.5%) emulsifying agent, 0% to 0.5% (preferably 0.005% to 0.06%) sweetening agent such as saccharin, 0% to 0.3% (preferably from 0.03% to 0.3%) flavoring agent, and the balance water.

Another optional component is a fluoride ion source. The sources of fluoride ions, or fluoride-providing compounds, are well known in the art as anticaries agents and also act as such agents in the practice of this invention as well as to inhibit pyrophosphatase. These compounds may be slightly soluble in water

or may, preferably, be fully water-soluble. They are characterized by their ability to release fluoride ions in water and by freedom from undesired reaction with other compounds of the oral preparation. Among these materials are inorganic fluoride salts, such as soluble alkali metal, alkaline earth metal salts, for example, sodium fluoride, barium fluoride, sodium fluorsilicate, ammonium fluorosilicate, sodium fluorozirconate, sodium monofluorophosphate, aluminum mono- and di-fluorophosphate, and fluorinated sodium calcium pyrophosphate. Alkali metal and tin fluorides, such as sodium and stannous fluorides, sodium monofluorophosphate (MFP) and mixtures thereof, are preferred.

The amount of fluoride-providing compound is dependent to some extent upon the type of compound, its solubility, and the type of oral preparation, but it must be a nontoxic amount, generally about 0.005 to about 3.0% in the preparation. In a dentifrice preparation, e.g. dental gel, toothpaste (including cream), an amount of such compound which releases up to about 5,000 ppm of F ion by weight of the preparation is considered satisfactory. Any suitable minimum amount of such compound may be used, but it is preferable to employ sufficient compound to release about 300 to 2,000 ppm, more preferably about 800 to about 1,500 ppm of fluoride ion. Typically, in the cases of alkali metal fluorides and stannous fluoride, this component is present in an amount up to about 2% by weight, based on the weight of the preparation, and preferably in the range of about 0.05% to 1%. In the case of sodium monofluorophosphate, the compound may be present in an amount of about 0.1-3%, more typically about 0.76%.

Still another optional component for use in the compositions of the present invention is an anticalculus agent. These agents include any which are effective against calculus such as pyrophosphate salts as disclosed in U.S. Patent 4,515,772, May 7, 1985 incorporated herein by reference. The preferred agents are mono, di, tri and tetra alkali metal and ammonium pyrophosphate. Such agents are used in amounts sufficient to reduce calculus. These amounts are preferably in an amount of at least about 1% P_2O_7, most preferably at least about 1.3%, most preferably at least about 1.5%.

Other anticalculus agents are metal ions such as zinc disclosed in U.S. Patent 4,022,880, May 10, 1977 to Vinson

incorporated herein by reference. Still others are polymers such as those described in U.S. Patent 4,661,341, April 28, 1987 to Benedict and U.S. Patent 3,429,963, February 25, 1969 to Shedlovsky, both of which are incorporated herein by reference. Such metals are used in an amount of from about 0.05% to about 5%, preferably about 0.5% to about 2%, while such polymers are used in amounts of from about 0.01% to about 10%, preferably from about 0.1% to about 5%.

Surfactants are also useful in the composition of this invention include many different materials. Suitable surfactants include any which are reasonably stable and function over a wide pH range. Included are non-soap anionic, nonionic, cationic, zwitterionic and amphoteric organic synthetic surfactants. Many of these are disclosed by Gieske et al. in U.S. Patent 4,051,234, September 27, 1988 incorporated herein in total by reference.

Preferred surfactants include alkyl sulfates. Any surfactant used is at a level of from about 0.2% to about 6%, preferably from about 0.6% to about 2% in a toothpaste and from about 0.01% to about 5%, preferably from about 0.1% to about 0.5% in a mouthwash.

The pH of the present compositions and/or its pH in the mouth can be any pH which is safe for the mouth's hard and soft tissues. Such pH's are generally from about 3 to about 10, preferably from about 4 to about 9.

Given below are non-limiting examples which illustrate the compositions of the present invention.

EXAMPLES I - IV

Given below are four examples of compositions.

Component	Weight %			
	(I)	(II)	(III)	(IV)
Water	20.518	20.518	14.069	11.165
Sorbitol (70%)	26.600	24.583	30.000	51.652
Glycerin	8.000	8.000	8.000	-
Sodium fluoride	0.243	0.243	0.321	0.243
Sodium acid pyrophosphate	1.650	1.650	1.650	-
Tetrasodium pyrophosphate	2.160	2.160	2.160	-
Tetrapotassium pyrophosphate (60-65%)	5.379	7.379	6.800	-
Monosodium phosphate	-	-	-	0.590
Trisodium phosphate	-	-	-	1.450
Saccharin	0.470	0.470	0.300	0.300
FD&C Blue No. 1	-	-	-	0.050
Titanium dioxide	0.500	0.500	0.700	0.525
Flavor	1.100	1.100	0.970	0.970
PEG-300	4.000	4.000	4.000	4.000

Triclosan	0.280	0.450	0.280	0.280
Sodium alkyl sulfate (27.9% aqueous solution)	6.000	6.000	6.000	6.000
Silica	20.300	20.300	22.000	20.000
Xanthan gum	0.600	0.600	0.500	0.475
Carbomer 956	0.200	0.200	0.250	0.300
Gantrez M-957	2.000	2.000	2.000	2.000
	100.000	100.000	100.000	100.000

EXAMPLES V - VI

Component	Weight %	
Ethanol	10	15
PEG-300	4	6
Flavor	0.1	0.15
Triclosan	0.03	0.03
Sodium Alyl Sulfate (27.9%)	1.6	1.8
Sorbitol	10	15
Glycerin	10	10
Gantrez M-957	2	2.5
Water	q.s. 100	q.s. 100

The above compositions are made in a conventional manner.

The performance of the above compositions of this present invention are superior due to the improved bioavailability of the triclosan antibacterial.

WHAT IS CLAIMED:

1. An oral composition comprising a noncationic water insoluble antibacterial, a polyethylene glycol solvent, a linear anionic polycarboxylate and water.

2. A composition according to Claim 1 wherein said antibacterial is a phenolic compound.

3. A composition according to either of Claims 1 or 2 wherein said polyethylene glycol has a molecular weight of from about 100 to about 1,000.

4. A composition according to any of Claims 1-3 wherein said polycarboxylate is an acrylic acid polymer.

5. A composition according to any of Claims 1-4 wherein said polymer is a copolymer of vinyl methyl ether and maleic anhydride.

6. A composition according to any of Claims 1-5 wherein said composition is a toothpaste or a mouthwash.

7. A composition according to any of Claims 1-6 wherein said composition is a toothpaste which in addition contains an abrasive and a binder.

8. A composition according to any of Claim 1-7 wherein said toothpaste also contains triclosan as the antibacterial agent.

9. A composition according to any of Claims 1-8 wherein said toothpaste contains a soluble fluoride ion source.

10. A composition according to any of Claims 1-9 wherein said toothpaste contains an anticalculus agent.

11. A composition according to any of Claims 1-10 wherein said anticalculus agent is a soluble pyrophosphate salt.

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 91/09377

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61K7/16

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61K

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category[10]	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	GB,A,2 200 551 (COLGATE-PALMOLIVE) 10 August 1988 cited in the application see page 22, line 12 - line 23; claims 1-33; table 3	1-11
X	FR,A,2 641 186 (COLGATE-PALMOLIVE) 6 July 1990 cited in the application see page 23, line 16 - page 24, line 4; claims 1-40; examples 1,2	1-10

* Special categories of cited documents:[10]

"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
26 MAY 1992	12.06.92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	WILLEKENS

Form PCT/ISA/210 (second sheet) (January 1985)

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. US 9109377 SA 55886

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on 26/05/92
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